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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,543	04/14/2000	EUGEN SCHWARZ	MERCK-2084	3926

23599 7590 09/05/2003

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/05/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,543

Applicant(s)

SCHWARZ ET AL.

Examiner

Susan Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-22, 24-25 is/are rejected.
- 7) ☒ Claim(s) 10 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, and
Amendment filed 05/28/03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the phrase "substantially homogenous distribution" or "solution is substantially homogeneous". Further clarification is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 6, 7, 9, 12, 13, 19-21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen et al. US 5,536,526.

Virtanen teaches compositions comprising about 94% to 98% by weight of xylitol and about 1% to about 5% by weight of acceptable polyol other than xylitol, e.g., mannitol, lactitol, sorbitol, maltitol and isomalt (column 5, lines 39-53). The composition can be prepared by agglomerating xylitol with polyol based syrup, granulating, drying in a fluidized bed to a water content of less than about 1%, and then directly compress into tablet (columns 6-8, and example 2).

Claims 1, 2, 4, 5, 9, 12-16, 18, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Olinger et al. US 5,204,115.

Olinger teaches compositions comprising about 95% to 99% xylitol, sweetener, e.g., saccharin, acesulfame K, cyclamate, or sucralose; and about 0.1% to about 5% of other polyol, e.g., mannitol, lactitol, sorbitol, maltitol, and isomalt (column 6, lines 53 through column 7, lines 16-22). The composition further comprises water-soluble additions, e.g., polydextrose containing citric acid (column 7, lines 51-55). Example 2 shows that xylitol was mixed with polydextrose syrup and water, the resulting wet granulate was placed in a fluidized bed at temperature of 50°C to obtain granule having moisture content of less than about 0.5%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-16, 18-22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. US 5,958,471 in view of Virtanen et al.

Schwarz teaches compositions comprising at least two polyols by co-spray-drying, wherein the composition comprises less than 10% mannitol (column 1, lines 51-65). The composition further comprises additives, such as citric acid sweetener, citric acid, or vitamins (columns 2-3). The composition is suitable for direct compacted articles, including tablet (column 3, lines 64-67). The composition is obtained by dissolving at least two polyols in aqueous solution and spraying the resulting aqueous solution in an air stream having temperature ranging from 120-300°C, the resulting is dried via a fluidized bed, wherein the mixture having water content of lower than 1% (columns 2-4, and examples).

Schwarz does not specifically teach the claimed ratios of the two polyols.

Virtanen teaches compositions comprising about 94% to 98% by weight of xylitol and about 1% to about 5% by weight of acceptable polyol other than xylitol, e.g., mannitol, lactitol, sorbitol, maltitol and isomalt (column 5, lines 39-53). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to use Schwarz's process to prepare Virtanen's composition with the expectation of at least similar results, because the references teach the advantageous results in the use of polyols, including xylitol to obtain a useful tableting aid having suitable hardness, friability and acceptable mouth feel.

Claims 1, 2, 4, 5, 9, 12-18, 21, 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olinger et al., and Mizumoto et al. US 5,576,014.

Olinger is relied upon for the reason stated above. Olinger is silent as to the teaching of pharmaceutical additives, e.g., antacid or analgesic agents (claim 17).

Mizumoto teaches compositions comprising xylitol, lactose, mannitol, glucose, sucrose, or sorbitol (column 6, lines 37-46). The composition further comprises pharmaceutical agents, such as analgesics and antacid (column 7, lines 62 through column 9, lines 1-43). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to combine Olinger's xylitol compressible composition with pharmaceutical agents of Mizumoto, because the references teach the advantageous of compressible tablet useful in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 05/28/03 have been fully considered but they are not persuasive.

Applicant's Declaration filed 07/01/02 has been fully considered. The Declaration compared the spraying techniques of Virtanen and Olinger to spraying techniques of the present invention. Based on the results, it was concluded that these different techniques result in different structural properties of the xylitol-sorbitol granulates. Applicant argues that this declaration provides more than sufficient evidence to establish the unobvious and novel differences between the claimed product and the

prior art product. In response to the applicant's argument, the particle surfaces with a needle structure is not excluded by applicants' claims.

Applicant requests that the 112 first paragraph be withdrawn because the experiments demonstrate that introducing sorbitol solution and xylitol to a granulator does not form a homogeneous solution prior to granulation, and therefore, according to the techniques of the present invention, the solution is inherently substantially homogeneous. However, nowhere in the specification, as well as the Declaration, is suggested that the solution is substantially homogeneous.

Allowable Claims

Claims 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in proper independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Application/Control Number: 09/529,543
Art Unit: 1615

Page 7

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600